



US009523653B2

(12) **United States Patent**  
**Che et al.**

(10) **Patent No.:** **US 9,523,653 B2**

(45) **Date of Patent:** **Dec. 20, 2016**

- (54) **DISPOSABLE TEST SENSOR WITH IMPROVED SAMPLING ENTRANCE**
- (71) Applicants: **Hongli Che**, Changsha (CN); **Shaobo Li**, Changsha (CN)
- (72) Inventors: **Hongli Che**, Changsha (CN); **Shaobo Li**, Changsha (CN)

- 5,126,034 A 6/1992 Carter et al.
- 5,128,015 A 7/1992 Szuminsky et al.
- 5,138,521 A 8/1992 Gemma et al.
- 5,264,103 A 11/1993 Yoshioka et al.
- 5,344,545 A 9/1994 Tsukada et al.
- 5,437,999 A 8/1995 Diebold et al.
- 5,575,895 A 11/1996 Ikeda et al.

(Continued)

(73) Assignee: **Changsha Sinocare Inc.**, High-Tech Zone, Changsha, Hunan (CN)

**FOREIGN PATENT DOCUMENTS**

- JP 2000-162176 A \* 6/2000 ..... G01N 27/416
- WO WO 2013117924 8/2013

(Continued)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 551 days.

**OTHER PUBLICATIONS**

(21) Appl. No.: **13/890,303**

JPO computer-generated English language translation of Nakajima et al. JP 2000-162176 A, patent published Jun. 16, 2000.\*

(22) Filed: **May 9, 2013**

(Continued)

**Prior Publication Data**

US 2014/0332414 A1 Nov. 13, 2014

(51) **Int. Cl.**  
**G01N 27/327** (2006.01)

(52) **U.S. Cl.**  
CPC ..... **G01N 27/3272** (2013.01); **Y10T 29/49117** (2015.01)

(58) **Field of Classification Search**  
CPC ..... G01N 27/3271; G01N 27/3272  
See application file for complete search history.

*Primary Examiner* — Alexander Noguera  
(74) *Attorney, Agent, or Firm* — Lambert & Associates;  
Gary E. Lambert; David J. Connaughton, Jr.

(57) **ABSTRACT**

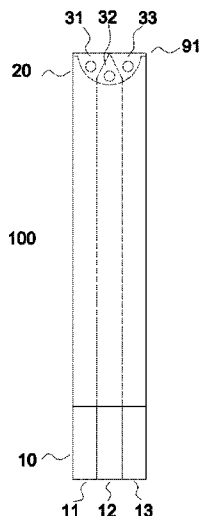
A disposable electrochemical test sensor designed to facilitate sampling of fluid samples. It has a fluid chamber having a novel extra wide sampling entrance, but no additional air escape vent. The chamber provides a reservoir from which a sample fluid can be drawn into the chamber through capillary action. The sampling entrance provided can draw fluid into the chamber through any part of the opening, allowing easy targeting the samples with small volume, picking up smeared samples, and added tolerance to users who jam the tip of the sensor into users' finger. The sampling entrance also serves as air escape vent. Such one opening sensor alleviates over-flow issue often encountered in convenient sensors.

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

- 4,431,507 A 2/1984 Nankai et al.
- 4,498,968 A 2/1985 Yamada et al.
- 4,534,356 A 8/1985 Papadakis
- 5,102,525 A 4/1992 Miyahara et al.
- 5,120,420 A \* 6/1992 Nankai ..... C12Q 1/001 204/403.11

**18 Claims, 9 Drawing Sheets**



(56)

References Cited

U.S. PATENT DOCUMENTS

5,582,697 A 12/1996 Ikeda et al.  
 5,665,222 A 9/1997 Heller et al.  
 5,708,247 A 1/1998 McAleer et al.  
 5,739,039 A 4/1998 Girault et al.  
 5,762,770 A 6/1998 Pritchard et al.  
 5,858,201 A 1/1999 Otsuka et al.  
 5,975,153 A 11/1999 Hill et al.  
 6,004,441 A 12/1999 Fujiwara et al.  
 6,071,391 A 6/2000 Gotoh et al.  
 6,125,292 A 9/2000 Uenoyama et al.  
 6,287,451 B1 9/2001 Winarta et al.  
 6,428,664 B1 8/2002 Bhullar et al.  
 6,540,891 B1 4/2003 Stewart et al.  
 6,592,746 B1 7/2003 Schmid-Schoenbein et al.  
 6,645,359 B1 11/2003 Bhullar et al.  
 6,767,440 B1 7/2004 Bhullar et al.  
 6,767,441 B1\* 7/2004 Cai ..... C12Q 1/004  
 204/403.03  
 6,787,013 B2 9/2004 Chang et al.  
 6,923,894 B2 8/2005 Huang et al.  
 6,942,770 B2 9/2005 Cai et al.  
 7,063,776 B2 6/2006 Huang  
 7,073,246 B2 7/2006 Bhullar et al.  
 7,118,667 B2 10/2006 Lee  
 7,276,146 B2 10/2007 Wilsey  
 7,288,174 B2 10/2007 Cui et al.  
 7,297,248 B2 11/2007 Bae et al.  
 7,386,937 B2 6/2008 Bhullar et al.  
 7,547,383 B2 6/2009 Cai et al.  
 7,641,785 B2 1/2010 Shinno et al.  
 RE41,264 E 4/2010 Cai et al.  
 7,727,367 B2\* 6/2010 Maruo ..... C12Q 1/005  
 204/403.02  
 7,740,746 B2 6/2010 Huang  
 7,802,467 B2 9/2010 Wang  
 7,824,616 B2 11/2010 Katsuki  
 7,955,484 B2 6/2011 Cai et al.  
 RE42,567 E 7/2011 Hodges et al.  
 RE42,953 E 11/2011 Crismore et al.  
 8,088,271 B2 1/2012 Fujiwara et al.  
 8,128,981 B2 3/2012 Popovich et al.  
 8,142,629 B2 3/2012 Miyazaki et al.  
 8,211,379 B2 7/2012 Burke et al.  
 8,222,044 B2 7/2012 Bhullar et al.  
 8,287,703 B2 10/2012 Bhullar et al.  
 RE43,815 E 11/2012 Crismore et al.  
 8,303,801 B2 11/2012 Wilsey  
 8,414,761 B2 4/2013 Gotoh et al.  
 8,430,999 B2 4/2013 Onoda et al.  
 8,480,869 B2 7/2013 Fujiwara et al.  
 8,535,497 B2 9/2013 Fujiwara et al.

8,540,864 B2 9/2013 Fujiwara et al.  
 8,551,308 B2 10/2013 Bhullar et al.  
 8,679,309 B2 3/2014 Beer et al.  
 2001/0034068 A1 10/2001 Spivey et al.  
 2004/0050717 A1 3/2004 Teodorczyk et al.  
 2005/0145490 A1 7/2005 Shinno et al.  
 2005/0214171 A1 9/2005 Gerstle et al.  
 2005/0269214 A1 12/2005 Lee  
 2005/0277850 A1 12/2005 Mace et al.  
 2007/0131548 A1 6/2007 Winarta et al.  
 2007/0235347 A1 10/2007 Chatelier et al.  
 2008/0006530 A1 1/2008 Winarta et al.  
 2008/0128278 A1 6/2008 Bae et al.  
 2008/0148873 A1 6/2008 Wang  
 2009/0078030 A1 3/2009 Jung  
 2009/0157001 A1 6/2009 Jones et al.  
 2009/0215159 A1 8/2009 Kirby  
 2011/0174613 A1 7/2011 Miyazaki et al.  
 2012/0174688 A1 7/2012 Calasso et al.  
 2012/0186996 A1 7/2012 Wilsey  
 2012/0234487 A1 9/2012 Wang  
 2013/0062221 A1 3/2013 Cai et al.  
 2013/0306472 A1 11/2013 Kaneda et al.  
 2013/0341208 A1 12/2013 Whyte et al.  
 2014/0021046 A1 1/2014 Huang et al.  
 2014/0054171 A1 2/2014 Feldman et al.  
 2014/0147912 A1 5/2014 Cho et al.  
 2014/0158553 A1 6/2014 Fujiwara et al.  
 2014/0174922 A1 6/2014 Beer et al.  
 2014/0262773 A1 9/2014 Riggles et al.

FOREIGN PATENT DOCUMENTS

WO WO 2013190072 12/2013  
 WO WO 2014140161 9/2014

OTHER PUBLICATIONS

Factors Affecting Blood Glucose Monitoring: Sources of Errors in Measurement, Barry H. Ginsberg, J Diabetes Sci. Technol. Jul. 2009; 3(4): 903-913.  
 USPTO Office Action—U.S. Appl. No. 14/099,418, Mar. 23, 2016.  
 USPTO Office Action—U.S. Appl. No. 14/153,654, Jun. 14, 2016.  
 USPTO Office Action—U.S. Appl. No. 14/184,764, Jul. 1, 2016.  
 Patent Cooperation Treaty International Search Report—WO2015126456—ISR-010, Dec. 22, 2014.  
 Patent Cooperation Treaty International Search Report—WO2015084448, Dec. 22, 2014.  
 Patent Cooperation Treaty International Search Report—WO2015105536, Dec. 22, 2014.

\* cited by examiner

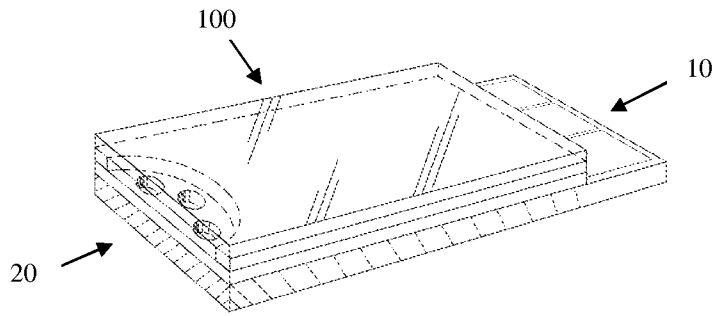


Fig.1

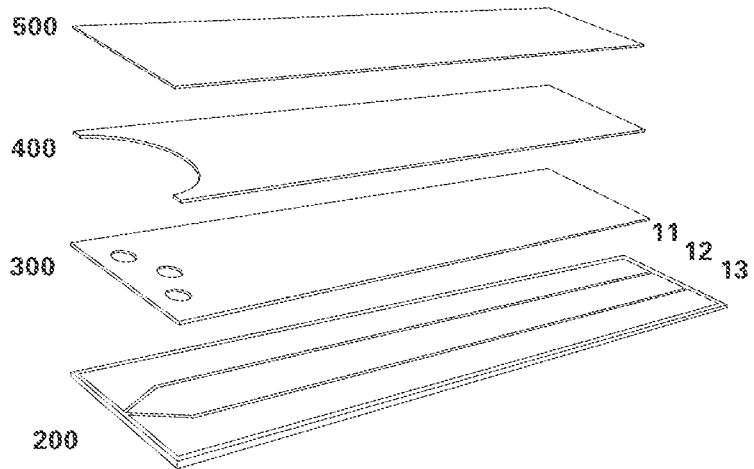


Fig.2

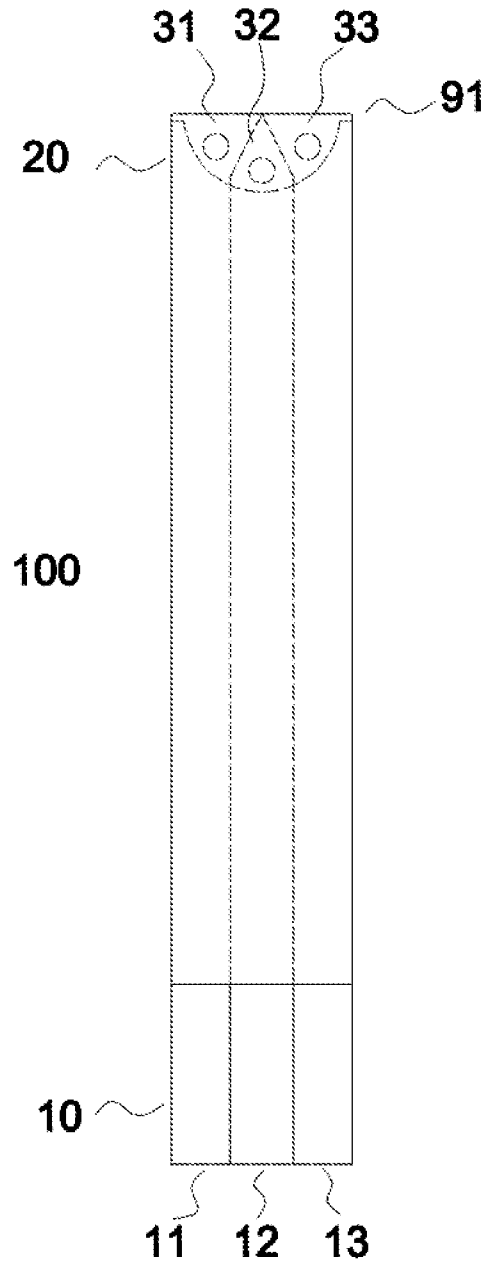


Fig. 3

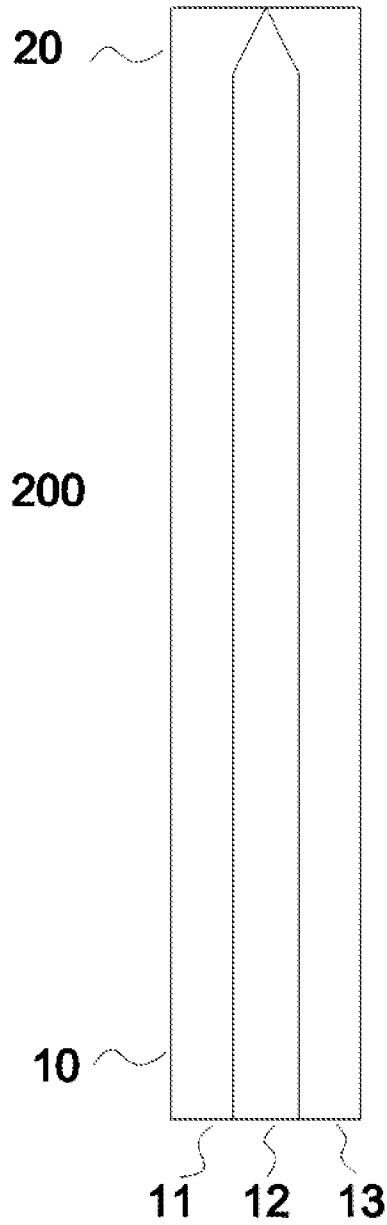


Fig. 4

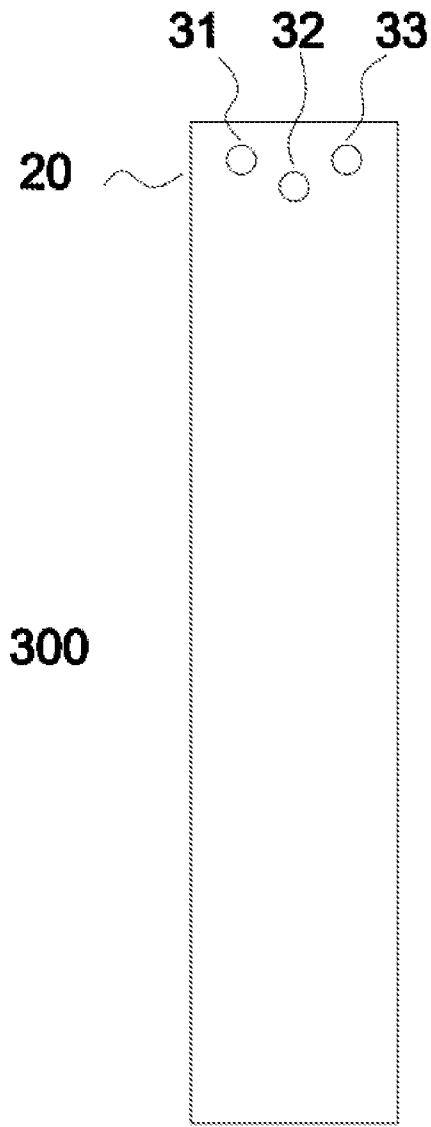


Fig. 5

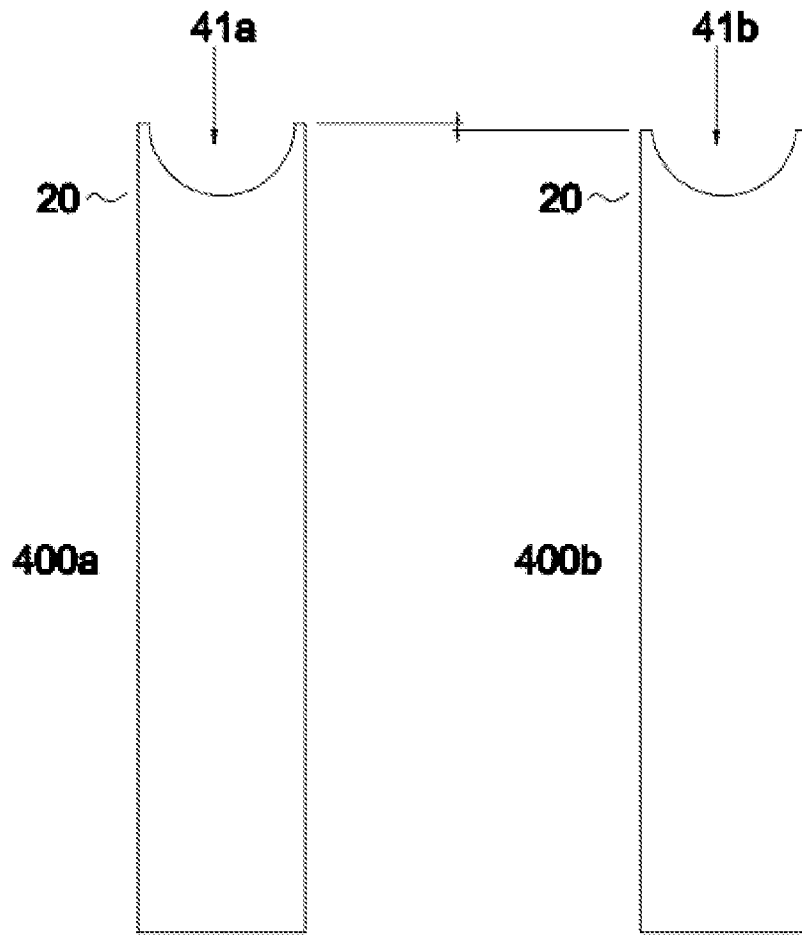


Fig.6a

Fig.6b

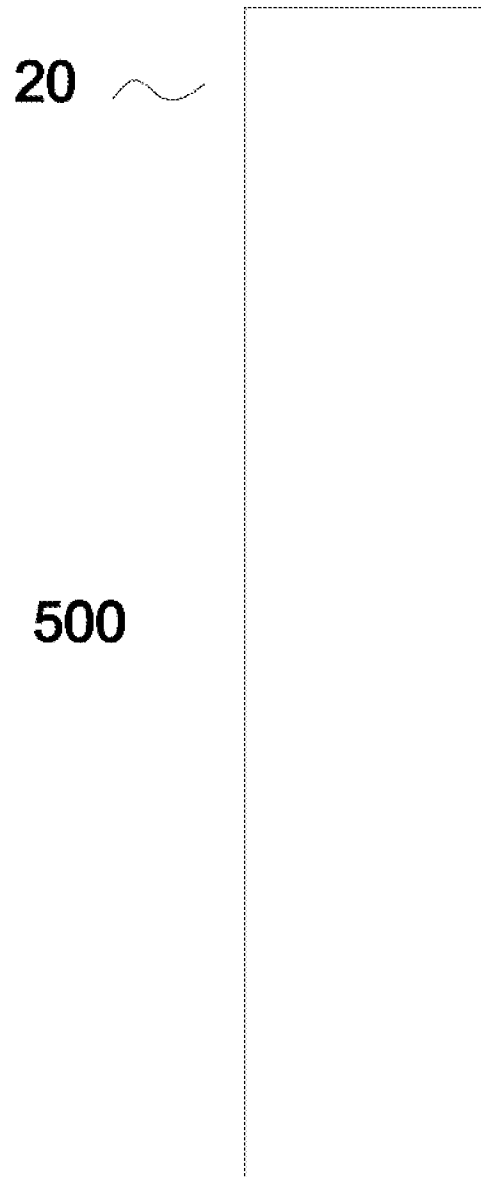


Fig. 7



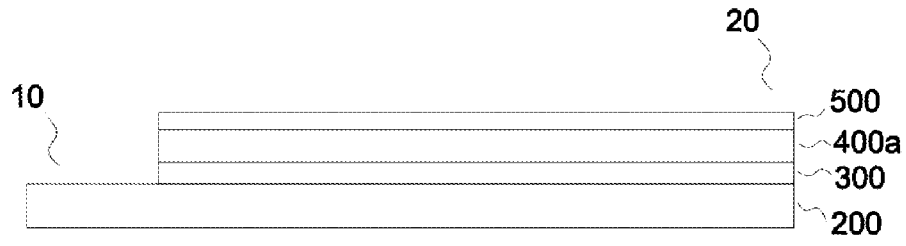


Fig. 8

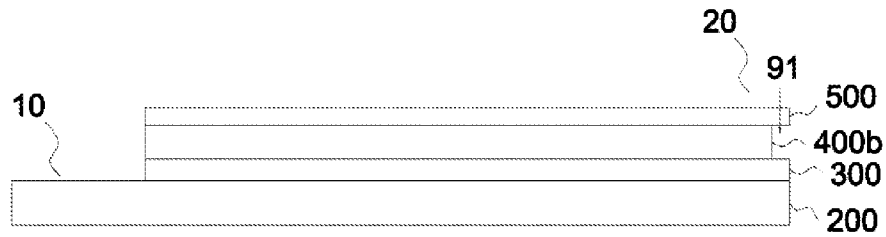


Fig. 9

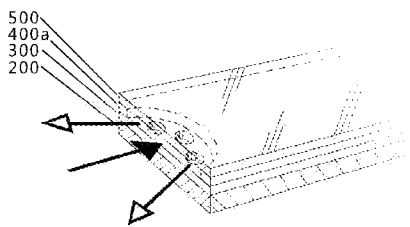


Fig. 10a

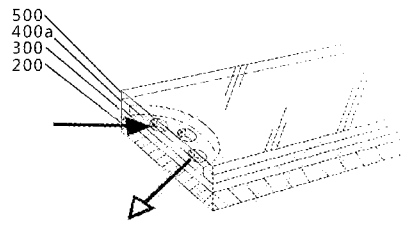


Fig. 10b

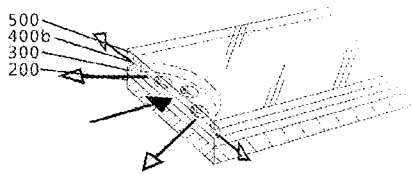


Fig. 11a

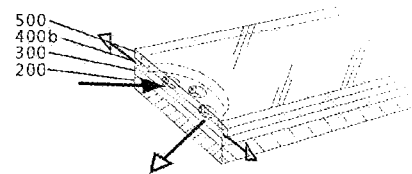


Fig. 11b

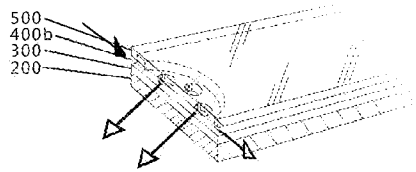


Fig. 11c

**DISPOSABLE TEST SENSOR WITH  
IMPROVED SAMPLING ENTRANCE**

## FIELD OF THE INVENTION

The present invention generally relates to a test sensor or strip. More specifically, the present invention generally relates to a disposable biosensor with a fluid chamber that is adapted to receive a fluid sample around with small volume. Still more specifically, the present invention generally relates an electrochemical biosensor with an extra wide sampling entrance. Still more specifically, the present invention relates methods of making and using the biosensors.

## BACKGROUND OF THE INVENTION

The use of disposable test sensors such as strips in the medical field for testing various analytes in body fluid is well known. The accurate determination of analytes in body fluids is of great importance in the diagnoses of certain physiological abnormalities. In particular, it is important that diabetic individuals frequently check their glucose level in their body fluids to regulate the glucose intake in their daily diets. The results of such tests can be used to determine the insulin dosage or other medication needs to be administered. In one type of blood-glucose testing system, test sensors, or called glucose strips, are used by diabetic individuals to test a sample of blood in connection with a hand-held meter. The glucose strips are used by millions of diabetics throughout the world on a daily base.

There are hundreds of brand names of glucose strips in the market. They are very similar in terms of sensor construction: i.e., a channel is formed between a generally U-shaped spacer and is adapted to receive blood from the opening end of the sensor through capillary action and escape air from the other end through an air escape vent. In order to reduce blood volume, thus reduce pain from piercing finger or other sampling points, the blood receiving chamber is usually small and, as a result, the sampling entrance is also relatively small. As the volume of fluid chambers in the sensors decreases, it becomes increasingly more difficult to fill the fluid chamber with the sample to be analyzed. It has been observed that users may abuse the test sensor by jamming the tip of the test sensor into the individual's finger, which very probably results in incomplete blood filling, non-continuous filling or wiggling of blood flow. Additionally, in some existing test sensors, it is difficult to position the fluid sample within the channel entrance opening especially for those diabetics who have poor vision and/or trembling hand. Besides, blood samples tend to smear around the tip of fingers or other sampling points. It becomes very difficult to draw such smeared blood into the sensor chamber. All of these phenomena may eventually lead to biased readings, and as a result, wrong dosage of insulin administration and even life threatening errors may occur.

Therefore, in order to reduce or eliminate such biased readings caused by such user action and/or reduce the difficulty in connection with sampling, it would be highly desirable to have a more user friendly test sensor that could easily target sample, easily draw sample into the sensor chamber, and alleviate incomplete filling, non-continuous filling and other issues that may result in inaccurate test results. The present disclosure is directed to a novel design and method to overcome one or more of the limitations in the prior arts.

## SUMMARY OF THE INVENTION

According to the first embodiment, a disposable electrochemical test sensor has a sample chamber having a novel

extra wide sampling entrance, but no additional air escape vent. Such a design is adapted to improve sampling of fluid samples. The fluid chamber provides a reservoir from which sample fluid can be drawn into the sample receiving chamber through capillary action. The extra wide sampling entrance provided by the present invention can draw blood into the chamber through any part of the opening end. Thus it allows easily targeting the samples with small volume, picking up smeared samples and alleviating jamming the opening end. The extra wide sampling entrance provided by the present invention also serves as the air escape vent. Such one opening sensor eliminates over-flow issue often encountered in conventional sensors. In preferred embodiments, the sensor consists of multiple layers which include a base layer having conductive coatings serving as working and reference electrodes; a second base layer used to define the electrode areas and hold chemistries; a first upper layer having semi-circular shape serving as spacer; and a second upper layer with a hydrophilic surface facing to the chamber. The upper and base layers are attached through adhesives or other ways to bond each other, such that the fluid chamber is formed between a portion of the lower layer surface and the upper layer surface at one end of the sensor, while the other end of the sensor having conductive layer exposed serve as electric contacts in connection with a monitor or meter.

According to the second embodiment, a disposable electrochemical test sensor has a sample chamber having a novel extra wide sampling entrance, but no additional air escape vent. Such a design is adapted to improve sampling of fluid samples. The chamber provides a reservoir from which sample fluid can be drawn into the sample receiving chamber through capillary action. The extra wide sampling entrance provided by the present invention can draw blood into the fluid chamber through any part of the front opening end, and can also draw blood into the fluid chamber through part of left side and part of right side near the opening end. The front opening and both side openings form a large opening, serving as blood sample entrance. Thus such unique design allows easily targeting the samples with small volume, picking up smeared samples and alleviating jamming of the opening by users' finger. The extra wide sampling entrance provided by the present invention also serves as the air escape vent. That is to say the air escape vent joins to the blood sampling entrance opening. Such two-in-one opening sensor eliminates over-flow issue often encountered in convenient sensors.

In preferred embodiments, the test sensor consists of multiple layers which include a base layer having conductive coatings serving as working and reference electrodes; a second base layer used to define the electrode areas and hold chemistries; a first upper layer having semi-circular shape serving as spacer; and a second upper layer with a hydrophilic surface facing to the chamber. The upper and base layers are attached through adhesives or other ways to bond each other, such that the fluid chamber is formed between a portion of the lower layer surface and the upper layer surface at one end of the sensor, while the other end of the sensor having conductive layers exposed serve as electric contacts in connection with a monitor or meter.

According to one method, an analyte concentration is measured. A disposable electrochemical test sensor is provided having a sample chamber having a novel extra wide sampling entrance, but no additional air escape vent. The chamber provides a reservoir from which sample fluid can be drawn into the sample receiving chamber through capillary action. The extra wide sampling entrance provided by

the present invention also serves as the air escape vent. In preferred embodiments, the sensor consists of multiple layers which include a base layer having conductive coatings serving as working and reference electrodes; a second base layer used to define the electrode areas and hold chemistries; a first upper layer serves as spacer which may have different shapes, such as circular arc, square, rectangular, triangle, regular trapezoid, inverted trapezoid; and a second upper layer with a hydrophilic surface facing to the chamber. The upper and base layers are attached through adhesives or other ways to bond each other, such that the fluid chamber is formed between a portion of the lower layer surface and the upper layer surface at one end of the sensor, while the other end of the sensor having conductive layers exposed serve as electric contacts in connection with a monitor or meter.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the test sensor of the present invention.

FIG. 2 is an exploded view of the test sensor of the present invention showing the four component layers.

FIG. 3 is a top view of the test sensor of the present invention consisting of four laminated layers according to one embodiment.

FIG. 4 is a top view of a first base layer to be used in forming a test sensor according to one embodiment.

FIG. 5 is a top view of the second base layer to be used in forming a test sensor according to one embodiment.

FIG. 6a is a top view of the first upper layer to be used in forming a test sensor according to the first embodiment.

FIG. 6b is a top view of the first upper layer to be used in forming a test sensor according to the second embodiment.

FIG. 7 is a top view of the second upper layer to be used in forming a test sensor according to one embodiment.

FIG. 8 is a side view of the test sensor according to the first embodiment of the present invention.

FIG. 9 is a side view of the test sensor according to the second embodiment of the present invention.

FIGS. 10a, 10b illustrate blood entering the fluid chamber and air escape for the test sensor according to the first embodiment of the present invention. Solid arrows and blank arrows denote blood sampling directions and air escape directions, respectively.

FIGS. 11a, 11b, 11c illustrate blood entering the fluid chamber and air escape for the test sensor according to the second embodiment of the present invention. Solid arrows and blank arrows denote blood sampling directions and air escape directions, respectively.

### DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

The test sensor of the present invention is directed to improve sampling entrance of the strip for the determination of an analyte concentration of in a fluid sample, such as blood. In one embodiment, a test sensor is adapted to receive a fluid sample from one end of the sensor, while the other end is connected with an instrument or meter. Analytes that may be measured include, but not limited to glucose, lactate, uric acid, creatinine, creatine, cholesterol, triglycerides, hemoglobin, bilirubin, alcohol, etc. The fluid sample may be any body fluid, thus, the analytes may be in, for example, a whole blood sample, a blood serum sample, a blood plasma

sample, other body fluids like tears, interstitial fluid and urine. In one preferred method, the testing equipment is a hand-held meter.

In a particular embodiment, the sensor comprises multiple layers which include a base layer having conductive coatings serving as working and reference electrodes; a second base layer used to define the electrode areas and hold chemistries; a first upper layer having semi-circular shape serving as a spacer; and a second upper layer with a hydrophilic surface facing to the chamber. The upper and base layers are attached such that the fluid chamber is formed between a portion of the lower layer surface and the upper layer surface at one end of the sensor, while the other end of the sensor having conductive layers exposed serves as electric contacts.

In one embodiment, the test sensor is an electrochemical test sensor. FIG. 1 shows a perspective view of the test sensor of the present invention. The sensor has a sensor body 100, an electric contact end 10 and sampling end 20. The electric contact end may have at least two contacts used for one working electrode and one reference electrode, respectively. In one preferred embodiment, the electric contact end has three electric contacts serving as contacts for a first working electrode 11; a second working electrode 13 and a reference electrode 12, respectively. In one embodiment, the test sensor consists of multiple layers which include a first base layer 200; a second base layer 300; a first upper layer 400; and a second upper layer 500, as shown in FIG. 2. FIG. 3 shows a top view of the test sensor consisting of four laminated layers according to one embodiment.

FIG. 4 shows a top view of a first base layer 200 to be used in forming a test sensor according to one embodiment. The first base layer 200 may be made from a variety of materials such as polymeric materials, coated with conductive materials such as carbon, various metals or metal oxides. The first base layer 200 with conductive coating serves as substrate of the test sensor and chamber forming layer. It also serves as electrodes at one end 20 and electric contacts at the other end 10. Non-limiting examples of polymeric materials, that may be used to form the base layer include, but not limited to polyethylene, polypropylene, polystyrene, polyvinyl chloride, and polytetrafluoroethylene, polycarbonate, polyethylene terephthalate, polyethylene naphthalate, polyimide and combinations thereof. The conductive coating may be formed by a variety of methods which are well known in the field including, but not limited to printing (e.g., screen-printing), coating (e.g., reverse roll), vapor deposition, sputtering, chemical deposition, and electrochemical deposition. The conductive coating may be on a whole piece of insulating material. If so, a desired number of electric conduits must be made. This can be achieved by etching/scrubbing the required number of conductive conduits. The etching process may be accomplished chemically, by mechanically scribing lines in the conductive layer, or by using a laser to scribe the conductive layer into separate conductive conduits. The conductive materials may be, but not limited to various carbon materials; various noble metals like gold, platinum, palladium, iridium, rhodium, ruthenium; various metal oxides like indium oxide, tin oxide; and combinations thereof.

FIG. 5 shows a top view of the second base layer to be used in forming a test sensor according to one embodiment. The second base layer 300 virtually has same width as the first base layer 200, but shorter in length at the end 10 to expose electric contacts. The second base layer 300 is made of electric insulating layer and it is shorter than the first base layer at the electric contact end 10 so that conductive coating

at the first base layer can be exposed for electric contacts when connected with test monitoring device like a hand-held meter. The second base layer **300** has at least one cutout at the end **20**. The cutout exposes a part of the conductive layer when laminated with the first base layer **200** and thus defines the electrode area. The cutout can also hold chemistries within the well formed. In one embodiment, the second base layer **300** has at least two such cutouts. In one preferred embodiment, the second base layer **300** has three round cutouts (**31**, **32**, **33**) at the end **20** serving as a first working electrode **31**; a reference electrode **32** and a second working electrode **33**. These cutouts have a diameter ranging from 0.1 mm to 2.5 mm. Preferably, the diameter is ranging from 0.5 mm to 1.5 mm. More preferably, it is around 1 mm. The electrode cutouts **31**, **32**, **33** have a certain depth, which depends on the thickness of the electric insulating materials used, thus form three wells and can hold chemistries within the wells. Preferably, the thickness of the electric insulating materials is from 0.01 mm to 0.2 mm. More preferably it is around 0.05 mm. In one embodiment of the present invention, the electrode cutouts **31**, **32**, **33** in the second base layer **300** have the same shape and dimensions. But they can have different shapes, dimensions and/or arrangement orders, without deviating from the scope and spirit of the present invention. The placement of all of the cutouts is such that they will be all positioned within the sample fluid chamber described above. The cutouts may be made by die cutting the insulating material mechanically, or cutting with a laser, and then fastening the material to the first base layer. An adhesive, such as a pressure-sensitive adhesive, may be used to secure the second base insulating layer **300** to the first base layer **200**. Adhesion may also be accomplished by ultrasonically bonding the second base layer **300** to the first base layer **200**. The second base layer **300** may also be made by screen printing an insulating material, by binding a photopolymer or by heat-sealing an insulating material over the first base layer **200**.

FIG. **6a** shows a top view of the first upper layer **400a** to be used in forming a test sensor according to the first embodiment. The first upper layer **400a** virtually has same width and length as the second base layer **300**. The first upper layer **400a** serves as a spacer in between the two base layers **200/300** and the second upper layer **500**. The first upper layer **400a**, or spacer, is also made of a plastic insulating material with glue or adhesive on both sides and creates the sample fluid chamber of the laminated body (FIGS. **1-3**). It contains a semi-circular shaped cutout **41a** at the end **20** which overlays the second base layer **300** with the open end corresponding to the open end of the laminated body described earlier. The semi-circular shaped cutout **41a** has a diameter of at least 1 mm. The diameter can be larger than or equal to the width of the first base layer **200** or second base layer **300**. Preferably, it is slightly smaller than the width of the second base layer **300**. More preferably, it is around 2 mm to 20 mm in the present invention. Assuming the test sensor or the component layers (**200**, **300**, **400a** and **500**) in the present invention have a width of around 6 mm, preferably, the diameter of the semi-circular shaped cutout is around 5.2 mm. Thus, a blood sample can enter the fluid chamber from any part of the entire opening end. A double coated, pressure-sensitive adhesive tape may be used as the first upper layer **400a**. The cutout **41a** creating the fluid chamber may have different shapes, including, but not limited to semi-circular, circular arc, square, rectangular, triangle, regular trapezoid, inverted trapezoid and etc. In one preferred embodiment, the cutout is in semi-circular shape. Obviously, the thickness and size of the cutout **41a** deter-

mine the volume of the capillary chamber. Preferably, the first upper layer **400a** has a thickness ranging from 0.01 mm to 0.5 mm, thus, the volume of the fluid chamber is about 0.1 to 5 microliter in the present invention.

FIG. **6b** shows a top view of the first upper layer **400b** to be used in forming a test sensor according to the second embodiment. The first upper layer **400b** is alternative to the first upper layer **400a**. The first upper layer **400b** also serves as a spacer in between the two base layers **200/300** and the second upper layer **500**. The first upper layer **400b** virtually has same width as the first upper layer **400a**, but it is slightly shorter in length at the end **20**, as a result, leaving openings at both corners after all four component layers **200**, **300**, **400b** and **500** are laminated. Such a unique design of the present invention forms an over 180° sampling entrance, even wider opening compared to the first embodiment described above. Therefore, a blood sample not only enters the fluid chamber from any part of the front opening, but also from both side opening of the test sensor at the end **20**. The first upper layer **400b**, or spacer, is also made of a plastic insulating material with glue or adhesive on both sides and creates the sample fluid chamber of the laminated body. It contains a semi-circular shaped cutout **41b** on the end **20** which overlays the second base layer **300** with the open end corresponding to the open end of the laminated body described earlier. The semi-circular shaped cutout **41b** has a diameter of at least 1 mm. The diameter can be larger than or equal to the width of the second base layer **300**. Preferably, it is slightly smaller than the width of the second base layer **300**. More preferably, it is around 2 mm to 20 mm. Assuming the test sensor or the component layers (**200**, **300**, **400a** and **500**) in the present invention has a width of around 6 mm, preferably, the diameter of the semi-circular shaped cutout is around 5.2 mm. A double coated, pressure-sensitive adhesive tape may be used as the first upper layer **400b**. The cutout **41b** creating the fluid chamber may have different shapes, including, but not limited to semi-circular, circular arc, square, rectangular, triangle, regular trapezoid, inverted trapezoid and etc. In one preferred embodiment, the cutout is in semi-circular shape. Obviously, the thickness and size of the cutout **41b** determine the volume of the capillary chamber. Preferably, the first upper layer **400b** has a thickness ranging from 0.01 mm to 0.5 mm, thus, the volume of the fluid chamber is about 0.1 to 5 microliter in the present invention.

The laminated body may also have a second upper layer **500**, as shown in FIG. **7**, bonded to the first upper layer **400a** or **400b**, but without an additional vent opening, which is needed in convenient sensors. It virtually has the same width and length as the second base layer **300** or first base layer **400a** in the first embodiment. While in the second embodiment, the second upper layer **500** may have the same width and length as the second base layer **300**, thus, it is slightly longer than the first base layer **400b**, such that side opening creates at the end **20**. Still in the second embodiment, the second upper layer **500** may have the same width as the second base layer **300**, but it can also have a length equal to or larger than the first upper layer **400b**. The second upper layer **500** is made of a plastic or polymer materials. Non-limiting examples of polymeric materials, that may be used to form the second upper layer **500**, include, but not limited to polyethylene, polyethylene terephthalate, polyethylene naphthalate, polyimide and combinations thereof. In one embodiment, the second upper layer **500** has a hydrophilic surface facing to the chamber to facilitate the capillary action. It should be understood that the entire side of the second upper layer **500** may be coated with a hydrophilic

substance and then bonded to the first upper layer **400a** or **400b**. In the present invention, it is not critical to have an additional vent opening at the second upper layer **500**.

Because of the unique design of the extra wide sampling entrance in the present invention, air escape is not an issue when a fluid sample such as blood enter the fluid chamber. Air can always find a way to escape from some part of the wide opening. Convenient test sensors always contain a vent opening for air escape when a fluid sample enters capillary channels. However, such vent opening may often cause problems, such as overflow, that may generate erratic test results. Besides, users may accidentally apply blood sample to the vent opening instead of the normal blood sampling entrance, that may also compromise the test results. The test sensor of the present invention with combination of sampling entrance and air escape vent in one extra wide opening virtually eliminates such issues.

FIG. **8** shows side view of the test sensor of the first embodiment consisting of four laminated layers including a first base layer **200**, second base layer **300**, first upper layer **400a** and second upper layer **500**.

FIG. **9** shows side view of the test sensor of the second embodiment consisting of four laminated layers including a first base layer **200**, second base layer **300**, first upper layer **400b** and second upper layer **500**. Note **91** denotes the side opening described earlier. Obviously, its thickness is the same as the first upper layer **400**. The length of the side opening **91** is preferably from 0.01 mm to 2.5 mm. More preferably, it is from 0.1 to 0.3 mm. Still more preferably, it is around 0.25 mm. It should be emphasized that the side opening **91** in the unique design of the present invention is just a part of the extra wide sampling opening. The side and front opening combine to form an over 180° sampling angle.

The advantage of the test sensor for blood sampling and air escape can be illustrated through FIGS. **10** and **11**.

FIGS. **10a**, **10b** illustrate blood entering the fluid chamber and air escape for the test sensor according to the first embodiment of the present invention. Note solid arrows and blank arrows denote blood sampling directions and air escape directions, respectively. Because of the extra wide sampling entrance opening of the present invention, blood sample can enter the fluid chamber from any part of the front opening, while air escapes from the rest of the opening. For example, if blood sample enters from the middle of the opening, air can escape from both side of the front opening (FIG. **10a**); if blood sample enters from one side of the front opening, air can escape from the other side (FIG. **10b**).

FIGS. **11a**, **11b**, **11c** illustrate blood entering the fluid chamber and air escape for the test sensor according to the second embodiment of the present invention. Note solid arrows and blank arrows denote blood sampling directions and air escape directions, respectively. Because of the extra wide sampling entrance opening of the present invention, blood sample can enter the fluid chamber from any part of the over 180° opening, while air escapes from the rest of the opening. For example, if blood sample enters from the middle of the front opening, air can escape from both side of the front opening as well as from the side opening **91** (FIG. **11a**); if blood sample enters from one side of the front opening, air can escape from the other side of the front opening as well as from the side opening **91** (FIG. **11b**); if blood sample enters from one side opening **91**, air can escape from the front opening as well as from the other side opening **91** (FIG. **11c**).

Obviously, by having a test sensor with the extra wide openings in the first embodiment or second embodiment, being adapted to receive a fluid sample, the test sensor of the

present invention more easily receives the fluid sample from a user and is more tolerant to users who jam the tip of the sensor into his/her finger, is more tolerant to fluid samples with very small volume (less than 1 microliter) and even smeared samples on the finger tip.

Referring back to FIGS. **1-3**, the electrode cutouts **31**, **32**, **33** may be loaded with chemistries that react with an analyte to produce detectable electrochemical signals. The chemistries may contain an enzyme, an antibody, an antigen, a complexing reagent, a substrate or combination thereof. The reagents are selected to react with the desired analyte or analytes to be tested so as to assist in determining an analyte concentration of a fluid sample. In one embodiment, the reagents typically contain an enzyme such as, for example, glucose oxidase, glucose dehydrogenase, cholesterol oxidase, creatinine amidinohydrolase, lactate oxidase, peroxidase, uricase, xanthine oxidase and etc. which reacts with the analyte and with an electron acceptor such as a ferricyanide salt to produce an electrochemically measurable species that can be detected by the electrodes. For example, if the analyte of the test sensor is glucose, then glucose oxidase or glucose dehydrogenase may be included as the enzyme; if the analyte of the test sensor is uric acid, then uricase may be included as the enzyme. It should be noted that in some cases more than one enzyme may be included to construct the test sensor in order to generate detectable electrochemical signal. For example, in order to make a test sensor for cholesterol, cholesterol esterase, cholesterol oxidase and peroxidase may be included in the sensor.

In order for the test sensor works effectively, the electrode cutouts **31**, **32**, **33** may comprise a mixture of a polymer, an enzyme, a surfactant, an electron acceptor, an electron donor, a buffer, a stabilizer and a binder. The electrode cutouts **31**, **32**, **33** may further include a mediator that is an electron acceptor and assists in generating a current that corresponds to the analyte concentration. The preferable mediators could be redox chemicals either in oxidized or reduced form. The mediator used in the present invention may include, but not limited to various metal or noble metal complexes such as potassium ferricyanide, potassium ferrocyanide, cobalt phthalocyanine, various ferrocenes, and various organic redox mediators such as methylene blue, methylene green, 7,7,8,8-tetracyanoquinodimethane, tetrathiafulvalene, toluidine blue, meldola blue, N-methylphenazine methosulfate, phenyldiamines, 3,3',5,5'-tetramethylbenzidine, pyrogallol, and benzoquinone, phenanthroline-5,6-dione and etc. For example, if the enzyme used to construct the test sensor is glucose oxidase or glucose dehydrogenase, then potassium ferricyanide may be included as redox mediator; if the enzyme used to construct the test sensor includes peroxidase, then potassium ferrocyanide may be included as redox mediator.

The electrode cutouts **31**, **32**, **33** include a first working electrode **31**, a second working electrode **33** and a reference electrode **32**. In one embodiment, the second working electrode **33** serves as a blank electrode without loading a chemistry that reacts with the analyte, such that background signal can be measured and be subtracted from the analyte signal resulted from the first working electrode **31**. In this embodiment, effect of interference substances on the analyte signal could be minimized. Still in this embodiment, the electric signals such as current, impedance at the working electrodes **31** and **33**, and time to obtain these signals could be used to estimate filling status of the fluid chamber (filled or not). Thus, this embodiment could alert under-fill of fluid samples.

Although the description of test sensor construction above describes construction for a single sensor, the design and materials used can also be used for making multiple sensors from one large piece of each layer material. This would be accomplished by starting with relative large pieces of the first base layer material, second base material, first upper layer material and second upper layer material. After a series of preparations described above, a plurality of multiple test sensors thus can be constructed to achieve mass production in a cost-effective way.

It should be noted that although the particular embodiments of the present invention have been described herein, the above description is merely for illustration purpose. Further modification and variations of the invention herein disclosed will occur to those skilled in the respective arts and all such modifications and variations are deemed to be within the scope of the invention as defined by the appended claims.

What is claimed is:

1. A sensor for sampling fluid samples comprising:

a substantially rectangular first base layer, the first base layer being coated with three substantially parallel spaced-apart strips of conductive coating on a top surface, the three strips of conductive coating extending approximately from a front edge to a rear edge of the first base layer, the three strips of conductive coating serving as electrodes to electronically connect the sensor to a meter at the rear edge of the first base layer;

a substantially rectangular second base layer attached to the top surface of the first base layer, the second base layer forming three apertures at a front end, the three apertures extending completely through from an upper surface to a bottom surface of the second base layer to form a first well, a second well, and a third well, one of the three apertures being positioned to align over one of the three strips of conductive coating of the first base layer;

wherein the three apertures are arranged to define an approximate isosceles triangle, the first well positioned at a vertex angle opposite to the isosceles triangle base which is defined by the second and third wells, the first well being farther from a front edge of the second base layer than the second and third wells, the first well forming one of a reference electrode and a working electrode, and wherein the second and third wells are each the other of the reference or working electrode from the first well, thereby providing accurate current so long as a fluid is contacting at least two of the three wells;

a substantially rectangular upper layer, the upper layer being positioned above the second base layer;

a spacer attached between a bottom surface of the upper layer and the upper surface of the second base layer, the spacer having a front edge, a first side edge and a second side edge, the spacer having a recessed portion on its front edge defining a fluid cavity, and being bounded by the recessed portion, the bottom of the upper layer, and the upper surface of the second base layer, wherein the fluid cavity is constructed and arranged to be in fluid communication with the first, second, and third well of the second base layer;

a first fluid inlet disposed along the front edge of the spacer, the first fluid inlet being an entrance to the fluid cavity;

wherein the shape and dimensions of the fluid cavity facilitate the drawing of a fluid sample into the fluid cavity using a capillary action; and

wherein the first fluid inlet serves as an air escape vent to facilitate the fluid sample being drawn into the fluid cavity using the capillary action.

2. The sensor of claim 1 wherein the second base layer is shorter in length than the first base layer to expose the electrodes at the rear edge of the first base layer.

3. The sensor of claim 1 wherein the first, second, and third well serve to hold a chemical selected to react with an analyte in a fluid sample to produce an electrochemical signal.

4. The sensor of claim 3 wherein the chemical is formed from substrates selected from the group consisting of: enzymes, antibodies, complexing reagents and combinations thereof.

5. The sensor of claim 3 wherein the chemical is formed from a mixture of a polymer, an enzyme, a surfactant, an electron acceptor, an electron donor, a buffer, a stabilizer and a binder.

6. The sensor of claim 3 wherein the chemical further comprises a mediator that is an electron acceptor, the mediator being redox chemicals either in oxidized or reduced form.

7. The sensor of claim 1 wherein the spacer is an electrically insulating material.

8. The sensor of claim 1 wherein the second bottom surface of the upper layer is a hydrophilic surface.

9. The sensor of claim 1 wherein the cut-out is centrally disposed along the front edge of the spacer.

10. The sensor of claim 1 wherein the spacer is a double-sided adhesive tape.

11. A sensor for sampling fluid samples comprising:

a substantially rectangular first base layer, the first base layer being coated with three substantially parallel spaced-apart strips of conductive coating on a top surface, the three strips of conductive coating extending approximately from a front edge to a rear edge of the first base layer, the three strips of conductive coating serving as electrodes to electronically connect the sensor to a meter at the rear edge of the first base layer;

a substantially rectangular second base layer attached to the top surface of the first base layer, the second base layer forming three apertures at a front end, the three apertures extending completely through from an upper surface to a bottom surface of the second base layer to form a first well, a second well, and a third well, one of the three apertures being positioned to align over one of the three strips of conductive coating of the first base layer;

wherein the three apertures are arranged to define an approximate isosceles triangle, the first well positioned at a vertex angle opposite to the isosceles triangle base which is defined by the second and third wells, the first well being farther from a front edge of the second base layer than the second and third wells, the first well forming one of a reference electrode and a working electrode, and wherein the second and third wells are each the other of the reference or working electrode from the first well, thereby providing accurate current so long as a fluid is contacting at least two of the three wells;

a substantially rectangular upper layer, the upper layer being positioned above the second base layer;



11

a spacer attached between a bottom surface of the upper layer and the upper surface of the second base layer, the spacer having a front edge, a first side edge and a second side edge, the spacer having a recessed portion on its front edge defining a fluid cavity, the fluid cavity bounded by the recessed portion, the bottom of the upper layer and the upper surface of the second base layer, wherein the fluid cavity is constructed and arranged to be in fluid communication with the first, second, and third well of the second base layer; and wherein the spacer is constructed and arranged to be slightly recessed in length relative to the first base layer, second base layer, and upper base layer when all are attached together leaving a first side opening defined by the spacer front edge, a first side edge of the second base layer and a first side edge of the upper layer, and the spacer leaving a second side opening defined by the spacer front edge, a second side edge of the second base layer, and a second side edge of the upper layer, wherein the first side opening, the second side opening and the front edge of the spacer together define a fluid inlet being an entrance to the fluid cavity that is accessible from an angle greater than 180 degrees such that a fluid may enter from the first side of the sensor, the second side of the sensor, and from a front of the sensor, the front being perpendicular to the first and second sides.

12. The sensor of claim 11 wherein the second bottom surface of the upper layer is a hydrophilic surface.

13. The sensor of claim 11 wherein the first, second, and third well serve to hold a chemical selected to react with an analyte in a fluid sample to produce an electrochemical signal.

14. The sensor of claim 11 wherein the first and second side openings are configured to allow a fluid to enter the fluid chamber through one of the two side openings when the first or second side edge is parallel to a surface that the fluid is on.

15. A sensor for sampling fluid samples comprising:

a substantially rectangular first base layer, the first base layer being coated with two substantially parallel spaced-apart strips of conductive coating on a top surface, the three strips of conductive coating extending approximately from a front edge to a rear edge of the first base layer, the three strips of conductive coating serving as electrodes to electronically connect the sensor to a meter at the rear edge of the first base layer;

a substantially rectangular second base layer attached to the top surface of the first base layer, the second base layer forming three apertures at a front end, the three apertures extending completely through from an upper surface to a bottom surface of the second base layer to form a first well, a second well, and a third well, one of the three apertures being positioned to align over one of the three strips of conductive coating of the first base layer;

12

wherein the three apertures are arranged to define an approximate isosceles triangle, the first well positioned at a vertex angle opposite to the isosceles triangle base which is defined by the second and third wells, the first well being farther from a front edge of the second base layer than the second and third wells, the first well forming one of a reference electrode and a working electrode, and wherein the second and third wells are each the other of the reference or working electrode from the first well, thereby providing accurate current so long as a fluid is contacting at least two of the three wells;

a substantially rectangular upper layer, the upper layer being positioned above the second base layer;

a spacer attached between a bottom surface of the upper layer and the upper surface of the second base layer, the spacer having a front edge, a first side edge and a second side edge, the spacer having a recessed portion on its front edge defining a fluid cavity, wherein the recessed portion of the spacer forms a semi-circular cross section of the fluid cavity having a straight edge of the cross sectional semicircle facing a front edge of the sensor, the fluid cavity being symmetrical about a lengthwise centerline of the sensor, and being bounded by the recessed portion, the bottom of the upper layer, and the upper surface of the second base layer, wherein the fluid cavity is constructed and arranged to be in fluid communication with the first and second well of the second base layer;

wherein the shape and dimensions of the fluid cavity facilitate the drawing of a fluid sample into the fluid cavity using a capillary action; and

wherein the spacer is constructed and arranged to be slightly recessed in length relative to the first base layer, second base layer, and upper base layer when all are attached together leaving a first side opening defined by the spacer front edge, and a first side edge of the second base layer and a first side edge of the upper layer, and the spacer leaving a second side opening defined by the spacer front edge, and a second side edge of the second base layer and a second side edge of the upper layer, wherein the first side opening, the second side opening and the front edge of the spacer together define a fluid inlet being an entrance to the fluid cavity that is accessible from an angle greater than 180 degrees.

16. The sensor of claim 15 wherein the second bottom surface of the upper layer is a hydrophilic surface.

17. The sensor of claim 15 wherein the first, second, and third well serve to hold a chemical selected to react with an analyte in a fluid sample to produce an electrochemical signal.

18. The sensor of claim 15 wherein the first and second side openings are configured to allow a fluid to enter the fluid chamber through one of the two side openings when the first or second side edge is parallel to a surface that the fluid is on.

\* \* \* \* \*